



December 1, 2021

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3758
Washington, DC 20250-3700

Docket No. FSIS-2020-0036
Submitted via *Regulations.gov*

Comments of the National Cattlemen's Beef Association on Labeling of Meat or Poultry Products Comprised of or Containing Cultured Animal Cells, 86 Fed. Reg. 49491.

The National Cattlemen's Beef Association (NCBA) appreciates the opportunity to comment on the U.S. Department of Agriculture Food Safety and Inspection Service (USDA-FSIS) advanced notice of proposed rulemaking related to the labeling of meat or poultry products comprised of or containing lab-grown animal cells. NCBA is the largest and oldest trade association representing U.S. cattle producers and the beef supply chain, with both direct members and over 250,000 cattle producers represented through its 44 state affiliate associations.

NCBA has a strong interest in ensuring reasonable, equitable, and science-based standards continue to serve as the basis for a comprehensive regulatory system over all meat food products, including meat analogs and substitute products made through novel technologies. NCBA supports the formal agreement entered into by FSIS and the Food and Drug Administration to jointly manage the production and sale of lab-grown protein products. As FSIS begins to chart the course for effectively bringing new food products to market that provide clear information to consumers, NCBA looks forward to the opportunity to engage. FSIS has a long history of ensuring that U.S. meat and poultry is the safest in the world; as new products come to market that intend to characterize themselves as "meat," FSIS has a duty to ensure that the same stringent standards of production and food safety are applied to all market participants.

Consumer Understanding

In January 2021, NCBA conducted research to gain insight relative to consumer perceptions of protein products comprised of or containing cultured animal cells (hereby referred to interchangeably as "lab-grown" or "cell-cultured") and subsequent understanding of potential labeling terminology.¹ The quantitative survey was conducted online, with a nationally representative sample of 1,000 consumers and was balanced to consensus on age, region, and gender. Additionally, those surveyed had to be involved, in some capacity, in their household's grocery shopping.

¹ Quantitative online survey conducted by the National Cattlemen's Beef Association of nationally representative sample (balanced by age, gender, and region), January 2021.



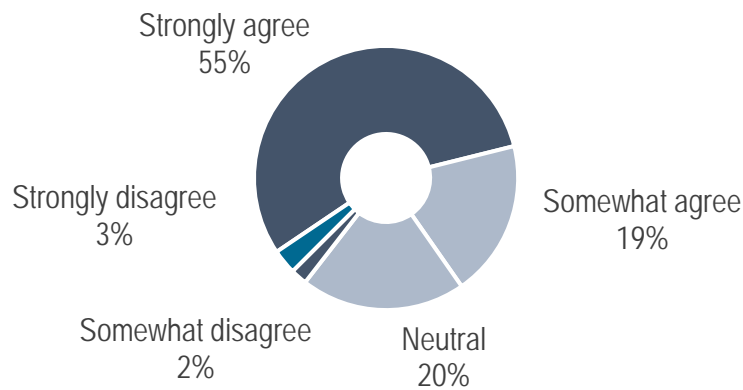
One important finding of NCBA's research is that consumer awareness and understanding of lab-grown meat is relatively low. When aided, only 13% selected being aware of the products, and when asked to provide a product definition after hearing one of several names for it, only 10% of consumers could provide an accurate definition. ²

Given the relatively new nature of products comprised of or containing cultured animal cells, and a demonstrated lack of consumer awareness, the standards USDA develops will play a crucial role in terms of ensuring adequate product safety and appropriate consumer understanding.

Existing federal law stipulates that food product labels bear a common or usual name as a "statement of identity" for products with no defined standard of identity. Such terms must communicate "on its own" (i.e. free from other supporting statements) that the product is different in some substantial way from the existing products with which it might be confused.

NCBA believes it is critically important for USDA to develop labeling standards which will empower consumers to differentiate between foods produced through cell-culture technology and conventional meat food products, and these standards should give consumers some idea of how these novel foods are produced.

Importantly, consumers agree. A good majority of respondents feel strongly that these products should be differentiated from their conventional counterparts on front-of-pack labeling: seventy-four percent of respondents agreed that restaurants and retailers should make it clear whether you are buying novel or conventionally produced meat, and fifty-five percent strongly agreed with the importance of differentiation.



*Please select your level of agreement with the following statement:
Restaurants and retailers should make it clear whether you are buying cell-cultured meat or conventionally produced meat.*

Defining "Beef"

Beef producers and retailers have spent generations building consumer demand for their product – consistently adapting to meet consumer desires and marketing products in a way that highlight the nutritional, economic, and environmental value of beef consumption. The beef value chain continually develops new ways to utilize beef in ways that maximize carcass value. Much of this research and product development is the product of the Beef Checkoff. The Beef Checkoff, established in 1985, requires that one dollar from the sale of every beef animal in the United States be paid into a common fund used for beef marketing and promotion. Perhaps the best example of the

² *Id.*



beef checkoff's work is the development and commercialization of the flat iron steak. This popular cut of beef was, until 2002, sold as part of the chuck roast. However, utilizing beef checkoff research funding, land grant researchers at the University of Florida and University of Nebraska discovered that a high-quality cut could be removed from the chuck to create additional value. This is just one example of the direct investment that cattle producers have made in developing consumer demand for beef that is traditionally raised and harvested. Under no circumstances should non-traditional meat products have access to terms whose value was established entirely by a competing production segment.

The adoption and use of previously established product names for lab-grown meat products fails to adequately disclose production disparities. NCBA recommends that FSIS develop food standards of identity specifically for this new category of protein, including qualifying language that mandates clear sourcing disclosure. NCBA requests that the agencies work with lab-grown protein companies to establish marketable product names that can be easily distinguished from traditionally raised and harvested meat products. Further, NCBA resists any effort to require production disclosures on the labels of traditionally raised and harvested meat. Animal harvest is our societal de facto meat source and is the presumed source for consumers who purchase meat. Traditionally raised and harvested meat should not be required to hold a label making such a claim.

Application of "Meat," "Meat Byproduct," or "Meat Food Product" to Cell-Cultured Protein

"Meat" is explicitly defined in the Code of Federal Regulations, the definition of which hinges entirely on the source of the product.³ "Meat," as defined by the CFR, is the muscle of an animal. Lab-grown protein companies claim that their products give consumers the opportunity to consume a protein product that does not come directly from an animal but is rather grown from animal cells. Such a product can, at best, be classified as a "meat byproduct" or "meat food product."⁴

In comments submitted to USDA and FDA on December 26, 2018, NCBA asserted that manufacturers of lab-grown protein products should make samples available prior to finalizing a regulatory framework. NCBA wishes to remind USDA of several important considerations in this regard, particularly in the context of labeling standards.

NCBA is aware that several manufacturers of lab-grown proteins contend their products are specifically designed to be comparable to conventionally produced meat products in terms of safety, composition, nutritional profile, organoleptic qualities, and function. These companies claim that the only difference between cell-cultured and traditional meat food products is the process by which the animal "parts" are grown and harvested. However, in the absence of independent, scientific evaluation of cell-cultured products, NCBA and other stakeholders have been forced to base assessments on the unverified claims and somewhat limited academic research on the topic. As Dr.

³ 9 CFR § 301.2(9) *The part of the muscle of any cattle, sheep, swine, or goats which is skeletal, or which is found in the tongue, diaphragm, heart, or esophagus, with or without the accompanying and overlying fat, and the portions of bone (in bone-in product such as T-bone or porterhouse steak), skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and that are not separated from it in the process of dressing.*

⁴ 9 CFR § 301.2(9) *Meat byproduct. Any part capable of use as human food, other than meat, which has been derived from one or more cattle, sheep, swine, or goats. This term, as applied to products of equines, shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats; 21 U.S. Code § 601 (j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.*



Rhonda Miller, past president of the American Meat Science Association and professor and research fellow at Texas A&M, said at FDA's first public meeting on cell-cultured products:

*"Meat scientists do not have enough information about cultured tissue to determine whether it should be called meat or how it should be regulated. Please note that samples of cultured tissue have not been available for evaluation of the safety, composition, nutritional bioavailability, functionality and sensory properties to understand how it compares to meat from conventional animal production."*⁵

The American Meat Science Association (AMSA) developed a Meat Science Lexicon for the standardization of various terms used in meat sciences.⁶ The Lexicon recognizes that while meat processing has become more complex as technologies have evolved, terminology used to describe these processes has failed to remain current.

AMSA defines meat as "Skeletal muscle and its associated tissues derived from mammalian, avian, reptilian, amphibian, and aquatic species harvested for human consumption. Edible offal consisting of organs and non-skeletal muscle tissues also are considered meat." The Lexicon also notes that "As of 2017, research is ongoing to produce animal-sourced food without harvesting animals by culturing muscle tissue from stem cells in a liquid medium (Hocquette, 2016). To be considered meat, these products must be comparable in composition and sensory characteristics to meat derived naturally from animals. In particular, the essential amino and fatty acid composition, macro and micronutrient content, and processing functionality should meet or exceed those of conventional meat."

To be clear, several in the scientific community have asserted that cultured muscle tissue is not technically meat as the latter is also a product of postmortem biochemistry. Researchers have further highlighted several challenges that remain with the functional engineering of meat including whether or not cell-cultured meat can provide essential minerals, creatine, carnosine, and B and D vitamins to the same extent as conventional meat.⁷

FSIS and FDA should refrain from finalizing the regulatory framework until independent researchers have the opportunity evaluate the biological, chemical, and ornithological characteristics of lab-grown protein products. While current sample products are proprietary and closely held, it is incumbent on lab-grown protein manufacturers to make samples available well before products are slated for introduction into the commercial market. Only through objective analysis can the federal government, scientific community, and other stakeholders truly understand the products in question.

Label Terminology

As USDA considers the clearest terminology to use when describing and labeling lab-grown meat, it must consider the product's source, economic impact to the industry and consumers, and the standards of identity that most adequately apply. Currently, as has been the case throughout history, meat has only one widely available production method – the raising and harvesting of animals. This is common knowledge. However, as technology evolves and consumers have access to meat byproducts and meat food products that have come to market through varying means of production, consumers must be informed about those practices.

⁵ FDA Public Meeting: Foods Produced Using Animal Cell-Culture Technology. (2018, July 12). Retrieved from <https://www.fda.gov/downloads/Food/NewsEvents/WorkshopsMeetingsConferences/UCM615856.pdf>

⁶ Seman, D. L. & Boler, D. D. & Carr, C. & Dikeman, M. E. & Owens, C. M. & Keeton, J. T. & Pringle, T. & Sindelar, J. J. & Woerner, D. R. & de Mello, A. S. & Powell, T. H., (2018) "Meat Science Lexicon", Meat and Muscle Biology 2(3). doi: <https://doi.org/10.22175/mmb2017.12.0059>

⁷ Cameron Faustman, Deb Hamernik, Michael Looper, Steven A Zinn, Cell-based meat: the need to assess holistically, Journal of Animal Science, Volume 98, Issue 8, August 2020, skaa177, <https://doi.org/10.1093/jas/skaa177>



USDA's consideration of consumer disclosure related to lab-grown meat can easily be distinguished from other debates related to consumer knowledge of production methods. For example, the ongoing public debate over GMOs differs drastically from the present question. While GMOs alter crop efficiency and resiliency, the production practices remain the same: seed is planted in the soil and grown, then harvested. Lab-grown meat has very little in common with traditionally raised and harvested meat. The production practices have no similarity.

Because these products have yet to reach consumers, no economic hardship would exist related to adjusting labels to satisfy heightened requirements or adjusting labels in a way that may create consumer confusion and loss in market share. The best time to establish these standards is now – the longer USDA waits to effectively establish standard of identity and labeling requirements for these products, the more costly compliance will be for regulated entities and consumers.

NCBA urges USDA to establish a regulatory standard of identity for food comprised of or containing cultured animal cells. NCBA is alarmed by the growing number of flagrantly deceptive food product labels proliferating the marketplace. Consumers have the right to expect that the information on food labels is truthful and not misleading, just as all food products should expect to compete on a fair, level playing field. The proposed rule presents fifteen general principles formulated by the agencies to answer petitions related to the establishment, revision, or elimination of a food standard. Food standards are used to ensure that products sold under particular names have the characteristics expected by consumers. FSIS has established food standards for nearly 80 meat and poultry products including “bologna,” “chimichanga,” and “beef stew.” The proposed principles will establish uniform criteria by which food identity standards are developed.

While the agencies have taken steps to define myriad food products, they have failed to provide definitions for raw commodities including meat, produce, and dairy. NCBA's goal is to ensure that the agencies, through their guiding principles, have the necessary charge to provide standards of identity for all food products.

In the 2005 proposed rule, FSIS and FDA concurred that food standards have been beneficial because they provide assurance to consumers of product uniformity with respect to certain significant characteristics of standardized foods, resulting in the expectation and belief of consumers that all products bearing a particular name will possess the same essential characteristics, irrespective of where they are purchased, or by whom they are manufactured or distributed. Food standards of identity are necessary to protect consumers against economic fraud, as well as support the hard work of American farmers. Establishing and standardizing guiding principles for food identities is necessary to ensure that the agencies and regulated stakeholders alike are held to understandable, uniform requirements.

Product Differentiation

As FSIS begins to consider how to appropriately name and label products that are comprised of or contain lab-grown protein, consumer awareness must remain a top priority. To understand more directly what this kind of product should be called and why, NCBA research evaluated a series of prospective names for the product, specifically:

- Cell-cultured meat
- Lab-grown meat
- Cultivated meat
- Synthetic meat



- Cell-based meat
- In-vitro meat

Consumers were provided the following definition *“Meat grown from the cells of animals, such a livestock, poultry, and seafood. It is made using novel technologies to create meat in a new way that is biologically the same as meat that comes from animals raised on farms or ranches”* and asked a series of questions to determine which labeling terminology has the greatest potential to empower consumers to make informed purchasing decisions.

NCBA’s research found that terms that alluded to how the meat is made resulted in greater understanding of the product, such as “cell-cultured” and “lab-grown.” Both terms elicited a partial or full understanding of the product from consumers, prior to defining it. Further, both names performed directionally higher when consumers were asked to score them on their fit with the definition provided and their ease of understanding them. Last, “lab-grown meat” was selected more often for being easy to understand.

Conversely, “cultivated” meat ranked highest in terms of sounding most appealing but scored second lowest in terms of fitting best with the definition provided. NCBA’s consumer survey substantiates misleading terms like “cultured,” “clean,” or “cultivated” fail to adequately describe the production practices to the everyday consumer.⁸ In determining how to most effectively name this class of products, the agency must focus on using clean and explicit language, as opposed to terms that have varying definitions.

Terms like “cultivated” and “synthetic,” that are likely less familiar to consumers in general, potentially create unintended perceptions. For example, significantly more consumers perceived “cultivated meat” as being raised on farms or ranches compared to the other names. As a result, when selecting which attributes that apply to that term, more consumers selected things like “is safe to eat” or “is natural,” while selecting things like “is processed” significantly lower than the other names. The term “cultivated meat,” consequently, is being perceived more positively—driven by the fact that more consumers thought it is raised on farms or ranches. “Synthetic meat,” on the other hand, seems to portray to consumers an enhanced meat product, or product altered to be different than traditional meat. Findings showed significantly more consumers agreed “synthetic meat” was processed and high in protein compared to other terms. These two terms should be avoided when defining this product due to their unintended and potentially inaccurate perceptions.

While FSIS (and industry) use “cultured” as a way to describe protein that is grown in an artificial manner, the average consumer likely associates “cultured” with refined taste. Further, when considering the synonyms of “cultured,” Webster’s Thesaurus lists “artistic, enlightened, civilized, educated, learned, and knowledgeable.”⁹ Especially in the context of a new product, consumers may be completely unaware that protein products exist which are grown in an artificial manner. Similarly, the term “clean” fails to adequately describe production practices while simultaneously diminishing competing products. The federal government has no role to play in characterizing one protein product as preferable to another – especially products with equivalent nutritional value. Finally, “cultivated” is a term that may be effectively applied to any animal protein product, or any food product for that matter, and fails to distinguish cell-cultured protein from traditionally harvested meat products.

NCBA recommends USDA adopt “lab-grown” as an unambiguous description for these products. Unlike the terms “cultured,” “clean” or “cultivated,” “lab-grown” provides a clear and unambiguous description that effectively

⁸ NCBA Consumer Survey, January 2021.

⁹ Cultured. 2021. In Merriam-Webster.com.

Retrieved November 29, 2021, from <https://www.merriam-webster.com/thesaurus/cultured>

distinguishes the product from traditionally harvested meat. NCBA also supports “artificially grown” or “artificially cultured” as alternatives. “Artificial” and “grown” are words used in the Webster’s definition of “cultured” and leaves little room for misinterpretation among consumers.

Blended Product Labeling

Similar to USDA’s existing requirements related to lean-to-fat ration within the ground beef standard of identity, NCBA encourages USDA to set a percentage threshold for consumer disclosure related to lab-grown meat content. While, by law, the maximum fat content for ground beef is 30%, a lab-grown ratio requirement for disclosure would simply set a threshold for consumer notification and should thus be significantly lower. All products sourced from lab-grown protein should provide clear indication to consumers including broths, bases, and flavors.

As USDA considers regulatory requirements related to blended product labeling and all other aspects of cell-cultured protein production, NCBA urges the mindful consideration of international trade standards and other international implications.

Conclusion

Thank you for the opportunity to provide input on this important topic. If you have any questions or need additional information, please contact NCBA’s Senior Executive Director of Government Affairs, Danielle Beck (dbeck@beef.org).

As USDA-FSIS further considers the best path forward in regulating new protein products, NCBA urges the continued prioritization of science-based policymaking and looks forward to continued engagement.

Sincerely,



Ethan L. Lane
Vice President, Government Affairs
National Cattlemen’s Beef Association

